AMENDMENT UNDER 37 C.F.R. § 1.114(c) Attorney Docket No.: Q95721

U.S. Application No.: 10/584,919

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the

application:

LISTING OF CLAIMS:

1. (currently amended): A cefuroxime axetil granule composition comprising a non-

crystalline cefuroxime axetil solid dispersion or a substantially amorphous cefuroxime axetil, a

sucrose fatty acid ester, a methacrylic acid-ethylacrylate copolymer, and a disintegrating agent,

wherein the methacrylic acid-ethylacrylate copolymer and the sucrose fatty acid ester are

present at a ratio of 1: 0.5 - 1.5 by weight and wherein the methacrylic acid-ethylacrylate

copolymer coats the cefuroxime axetil.

2. (original): The cefuroxime axetil granule composition of claim 1, wherein the

disintegrating agent is selected from the group consisting of fine crystalline celluloses, cross-

linked sodium carboxymethyl celluloses, cross-linked polyvinyl pyrrolidones, ion exchange

resins, alginic acid, sodium starch glycolate and a mixture thereof.

3. (original): The cefuroxime axetil granule composition of claim 1, wherein the

amounts of the sucrose fatty acid ester, the methacrylic acid-ethylacrylate copolymer and the

disintegrating agent are 0.5 to 10, 0.5 to 10, and 0.1 to 10 parts by weight, respectively, based on

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1 part by weight of a non-crystalline cefuroxime axetil solid dispersion or a substantially

amorphous cefuroxime axetil.

4. (original): The cefuroxime axetil granule composition of claim 1, which further

comprises a coating material and a pharmaceutically acceptable additive.

5. (original): The cefuroxime axetil granule composition of claim 4, wherein the

coating material is an enteric coating material.

6. (original): The cefuroxime axetil granule composition of claim 4, wherein the

amounts of the coating material and the pharmaceutically acceptable additive are 0.2 to 10 and

0.02 to 50 parts by weight, respectively, based on 1 part by weight of a non-crystalline

cefuroxime axetil solid dispersion or a substantially amorphous cefuroxime axetil.

7. (original): A process for preparing a cefuroxime axetil granule having the

composition of claim 1 comprising the steps of:

1) mixing the sucrose fatty acid ester and methacrylic acid-ethylacrylate copolymer,

followed by melting the mixture with heating;

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2) dispersing the disintegrating agent, and the non-crystalline cefuroxime axetil solid

dispersion or substantially amorphous cefuroxime axetil in the molten mixture obtained in step

1); and

3) cooling the dispersion obtained in step 2), followed by pulverizing the cooled

dispersion to obtain the granule.

8. (original): The process of claim 7, wherein the melting temperature in step 1) is in

the range from 60 to 75 $^{\circ}$ C.

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